K062994 (pg 1 of 2)

BIOMET
ORTHOPEDICS, INC.

510(k) Summary

Date Prepared: March 7, 2007

MAR 0 9 2007

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Lateralized Taperloc® Microplasty™ Femoral Components

Common Name: Total hip replacement device

Classification Name:
Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (21 CFR 888.3330)
Product Code: KWA

Subsequent Product Codes:
KWZ, JDL, JDI, LZO, MEH, LPH, MBL, KWY

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Taper 2™ Porous femoral Stem - K050441

Device Description: The Lateralized Taperloc® Microplasty™ Femoral Components are straight, collarless, flat, tapered stems designed to match the geometry of the femur. The stems are proportionally sized and shaped in sizes 5.0mm to 25.0mm diameters. The stems are manufactured from titanium alloy (Ti-6Al-4V) conforming to ASTM F-136 or F-1472 and a proximal portion of each femoral stem is covered with Biomet's full plasma spray porous coating.

Intended Use: The Lateralized Taperloc® Microplasty™ Femoral Components are indicated for use in patients requiring hip replacement due to the following:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
5) Revision of previously failed femoral head resurfacing component

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The Lateralized Taperloc® Microplasty™ Femoral Components are intended for uncemented use only.

Specific indications for compatible components that can be used with the Lateralized Taperloc® Microplasty™ femoral Components include:

Constrained Liners (K030047)
Constrained liners are intended for general use in skeletally mature individuals undergoing primary and/or revision surgery at high risk of hip dislocation due to history of prior dislocation, joint or bone loss, soft tissue laxity, neuromuscular disease, or intra-operative instability and for whom all other options to constrained acetabular components have been considered.

Summary of Technologies: The overall design, materials and processing methods are similar to the predicate device

Non-Clinical Testing: Mechanical testing has demonstrated equivalence between the Lateralized Taperloc® Microplasty™ Femoral Components and the predicates.

Clinical Testing: None provided

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Manufacturing Corporation
c/o Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 East Bell Drive
Warsaw, Indiana 46582

MAR 0 3 2007

Re: K062994
Trade/Device Name: Lateralized Taperloc® Microplasty™ Femoral Components
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.
Regulatory Class: Class III
Product Code: KWA, KWZ, JDL, JDI, LZO, MEH, LPH, MBL, KWY
Dated: February 14, 2007
Received: February 15, 2007

Dear Ms. Beres:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

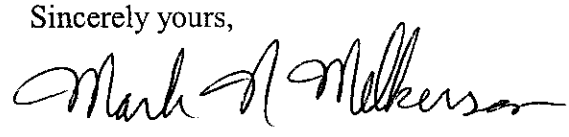
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062994

Device Name: Lateralized Taperloc® Microplasty™ Femoral Components

Indications For Use:

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K062994 B-1